REMARKS

Claims 1 through 28 are pending. Claims 8, 9, and 18 are objected to as being dependent from a rejected base claim, but would be allowable if rewritten in independent form. Claims 1–7, 10–17, and 19–28 stand rejected. Applicant respectfully requests reconsideration and allowance of all claims of this application.

Claims 1 and 10 stand rejected under 35 U.S.C. § 102(e) as assertedly anticipated by U.S. Pat. No. 6,155,257 to Lurie et al. The Office Action asserts that Lurie teaches a method comprising the steps of sensing a carbon dioxide level associated with a patient breathing interface; determining if the level of carbon dioxide is increasing or decreasing; if decreasing, determining if the level of carbon dioxide has crossed the threshold parameter; increasing the breathing gas pressure provided to the breathing interface; decreasing the breathing gas pressure provided to the patient breathing interface after a predetermined period of time; and increasing and decreasing the breathing gas pressure maintaining a positive pressure sufficient to sustain open the airway of a patient wearing the breathing interface.

"To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996). "The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (Bd. Pat. App. & Int. 1990); *see also In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) ("Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all the elements of the claimed invention be described in a single reference."); *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984) ("Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim."). "Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference." *Levy* at 1462.

Where there are differences between the referenced disclosure and the claim, a rejection under § 102 is improper. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985). "There must be no difference between the claimed invention and the referenced disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991).

Lurie et al. '257 does not disclose every element of claim 1 of the present application. The passage of Lurie et al. '257 cited in the Office Action provides that "information *regarding the pressure in the patient's airway* may be employed to control the proper volume of respiratory gases delivered to the patient, [or] to provide positive pressure breaths with the patient's spontaneous ventilatory pattern." Column 13, lines 51 through 55 (emphasis added). The method described in Lurie et al. '257 uses the pressure in the patient's airway to control respiratory gases delivered to the patient. The method in claim 1 of the present invention provides breathing gas based on carbon dioxide level in a patient breathing interface.

In fact, the purpose of the device in Lurie et al. '257 is to "provide[] for the coordination of patient ventilation with chest compressions." Column 6, lines 53 through 54. The embodiment of that device in the passages identified by the Office Action uses an airway pressure sensing device. Column 13, lines 42 through 43. This airway pressure device controls the respiratory gases delivered to the patient. Column 13, lines 51 through 55. There is no disclosure of providing breathing gas based on carbon dioxide level in the breathing interface.

Lurie et al. '257 does provide that carbon dioxide sensors may be coupled to the airway pressure sensing module. Column 13, line 47. But this carbon dioxide sensor merely provides data to an optional display on a control panel to visually display physiologic characteristics of the patient, and is not used in the control of breathing gas. Column 13, lines 55 through 60. The purpose of such a display is to "provide feedback

to the rescuer regarding various physiological parameters." Column 4, lines 16 through 17.

Lurie et al. '257 does not disclose the claimed elements of:

> determining if the level of carbon dioxide is increasing or decreasing; if the level is decreasing, determining if the level of carbon dioxide has crossed a threshold parameter; if the carbon dioxide level has crossed the threshold parameter, increasing the breathing gas pressure provided to the patient breathing interface; decreasing the breathing gas pressure provided to the patient breathing interface after a predetermined period of time; the increasing and decreasing of breathing gas pressure maintaining a positive pressure sufficient to sustain open the airway of a patient wearing the breathing interface

as claimed in claim 1 of the present application. Nor has the Office Action "identif[ied] wherein each and every facet of the claimed invention is disclosed in the applied reference." *Levy* at 1462.

For at least these reasons, the rejection under Lurie et al. '257 is improper and Applicant respectfully requests that the rejection of claim 1 based on Lurie et al. '257 be withdrawn.

The Office Action further states that the operation of the device of Lurie et al. '257 teaches the recited method steps in claims 10, 17, and 21, because the module 122 receives data from the sensors and compares it to predetermined minimum and maximum values and controls the ventilator to maintain the actual value between the predetermined minimum and maximum values.

Initially, it is respectfully pointed out that claims 17 and 21 were not identified as being rejected under § 102(e) as assertedly anticipated by Lurie et al. '257. Applicant presumes that this was merely an oversight and will address these claims as the Office Action applies Lurie et al. '257 thereto. Applicant reserves the right to address rejections of claims 17 and 21 if this presumption is incorrect.

As described above, Lurie et al. '257 does not teach, disclose, or even hint at the use of carbon dioxide data for anything other than to display on a control panel. Specifically, Lurie et al. '257 does not disclose:

—the claim 10 elements of determining if the sensed level of carbon-dioxide is increasing or decreasing; if the sensed carbon-dioxide level is increasing, determining if the sensed carbon-dioxide level has crossed a first threshold parameter; if the sensed carbon-dioxide level has crossed the first threshold parameter, decreasing the breathing gas pressure provided to the patient breathing interface; if the sensed carbon-dioxide level is decreasing, determining if the sensed carbon-dioxide level has crossed a second threshold parameter; if the sensed carbon-dioxide level has crossed the second threshold parameter, increasing the breathing gas pressure provided to the patient breathing interface; and the increasing and decreasing of breathing gas pressure maintaining a positive pressure sufficient to sustain open the airway of a patient wearing the breathing interface;

—the claim 17 elements of determining if the sensed level of carbon-dioxide is increasing or decreasing; if the sensed level of carbon-dioxide is decreasing, determining whether the sensed level of carbon-dioxide at or below a threshold level; if the sensed level of carbon-dioxide is at or below the threshold level, increasing the pressure of the breathing gas for a fixed period of time; decreasing the pressure of the breathing gas upon expiration of the fixed period of time; the increasing and decreasing of the pressure of the breathing gas maintaining a positive pressure sufficient to sustain open the airway of the patient; or

—the claim 21 elements of if the level of carbon-dioxide vented is decreasing, determining of the level of carbon-dioxide is at or below a threshold value; if the level of carbon-dioxide vented is at or below the threshold value, providing a first positive airway pressure to the patient breathing interface for a fixed period of time; and upon the expiration of the fixed period of time providing a second positive airway pressure to the patient breathing interface.

Nor has the Office Action "identif[ied] wherein each and every facet of the claimed invention is disclosed in the applied reference." *Levy* at 1462.

Absent such disclosures of every element of the claims of the present application, a rejection under § 102 based on the Lurie et al. '257 reference is improper. *See, e.g., Titanium Metals Corp.* 778 F.2d at 780. Applicant, therefore, respectfully requests that the rejection of claims 10, 17, and 21 be withdrawn.

Claims 2–4, 7, 11–13, 16, 19, and 20 stand rejected under 35 U.S.C. § 103(a) as assertedly unpatentable over Lurie et al. '257 in view of U.S. Pat. No. 6,099,481 to Daniels et al. These are all dependent claims that depend from one of the independent claims 1, 10, or 17 discussed above. Because these dependent claims all depend from allowable independent claims, it is respectfully submitted that the dependent claims are also allowable.

Claims 5, 6, 14, and 15 stand rejected under U.S.C. § 103(a) as assertedly unpatentable over Lurie et al. '257 and Daniels et al. '481 and further in view of U.S. Pat. No. 5,193,544 to Jaffe. These are all dependent claims that depend from one of the independent claims 1 or 10 discussed above. Because these dependent claims all depend from allowable independent claims, it is respectfully submitted that the dependent claims are also allowable.

Claims 23 and 25–28 stand rejected under 35 U.S.C. § 103(a) as assertedly unpatentable over U.S. Pat. No. 5,954,050 to Christopher in view of U.S. Pat. No. 5,193,544 to Jaffe. Applicant notes that claim 22 was not identified as being rejected under § 103(a) as assertedly unpatentable over Christopher '050 in view of Jaffe '544. Applicant presumes that this was merely an oversight and will address these claims because these references are applied against claim 22. Applicant reserves the right to address rejection of claim 22 if this presumption is incorrect.

Each prior art reference and the claimed invention must be evaluated as a whole in determining obviousness. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985). It is not permitted to first determine what it was the inventor did and then select only those facts from the prior art which may be modified to construct the invention from the prior art. *In re Shuman*, 361 F.2d 1008 (CCPA 1966). One "cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention." *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 887 (Fed. Cir. 1988). It is not proper that prior art references be cobbled together and "employed as a mosaic to recreate a facsimile of claimed invention." *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1552 (Fed. Cir. 1983).

In the present case, the combination suggested by the Office Action would not result in the claimed invention, as is seen when the claimed invention and the prior art are considered as a whole. The invention claimed in claim 22 is a "system for administering a breathing gas to a patient breathing interface comprising . . . logic for increasing and decreasing the level of the positive pressure breathing gas based on the level of carbon dioxide detected to maintain open the airway of a patient." In contrast, the device disclosed in Christopher '050 supplies "[a] substantially constant flow of oxygen/air . . . through one of the lumens of the transtracheal catheter into the patient's trachea to augment the patient's spontaneous breathing." Column 3, lines 58–61. This teaching of a constant flow of oxygen/air is significantly different from the claimed increasing and decreasing the positive pressure breathing gas based on the level of carbon dioxide detected, as claimed in claim 22 of the present invention.

Christopher '050 does disclose a sensor for measuring the carbon dioxide concentration of air exhaled by the patient. But Christopher '050 also notes that "the gas exiting the mouth or nose during the initial phase of each exhalation provides a relatively inaccurate measurement of CO_2." Column 7, lines 20–22. The Christopher '050 device measures carbon dioxide through a transtracheal catheter placed relatively close to the bronchial tubes. Column 7, lines 39–45. This is purely a measurement of carbon dioxide

exhaled by the patient, and does not include any logic to adjust the positive pressure breathing gas based on the level of carbon dioxide detected, as claimed in claim 22 of the present invention.

Christopher '050 does disclose a computer processor 60 that receives respiration data, including data from a capnometer 87. "This respiration data is recorded or stored by a data storage/recorder unit 61 for later review." Column 5, lines 20–22. "This data is recorded to monitor the patient's respiration patterns over time for subsequent analysis." Column 3, lines 64–66. There is no indication that there is any logic at all in the device disclosed in Christopher '050 for increasing and decreasing the positive pressure breathing gas based on the level of carbon dioxide detected, as claimed in claim 22 of the present invention. On the contrary, any carbon dioxide data collected is merely stored for later analysis.

The claims of the present application stand rejected based upon a cobbling together of various individual elements of prior art references. "It is impermissible within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau*, 353 F.2d 238, 241(CCPA 1965); *see also Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448-49 (Fed. Cir. 1986). The prior art references must be considered as a whole, not just for the individual elements thereof. "[T]he inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed." *Hartness Int'l, Inc. v. Simplimatic Eng. Co.*, 819 F.2d 1100, 1108 (Fed. Cir. 1987).

Thus, it would not be obvious to combine individual elements from Christopher '050 and Jaffe '544 to arrive at the present invention, especially in light of the lack of any suggestion in the prior art to do so. Even if such combination were to be made, the combination would not lead to the present invention, because neither reference teaches, suggests, or even hints at logic for increasing and decreasing the positive pressure

breathing gas based on the level of carbon dioxide detected, as claimed in claim 22 of the present invention. In fact, Christopher '050 teaches quite the contrary—providing a constant flow of oxygen/air and obtaining respiratory data to be saved for later evaluation.

For at least these reasons, the rejection of claim 22 under 35 U.S.C. § 103(a) is improper, and Applicant respectfully requests that the rejection of claim 22 be withdrawn.

Claims 23 and 25–28 are dependent from claim 22 and are allowable as being dependent from an allowable base claim.

Claim 24 stands rejected under 35 U.S.C. § 103(a) as assertedly unpatentable over Christopher '050 in view of Jaffe '544 and further in view of U.S. Pat. No. 3,921,628 to Smythe et al. Claim 24 is a dependent claim that depends from independent claim 22, discussed above. Because this dependent claim depends from an allowable independent claims it is respectfully submitted that the dependent claim is also allowable.

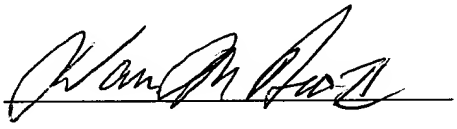
CONCLUSION

For at least the above reasons, the rejections in the Office Action are improper. Applicant believes that all of the claims in this case are in condition for allowance and respectfully solicits an indication to that effect. If the Examiner believes that additional discussions or information might advance the prosecution of this case, the Examiner should feel free to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

CALFEE, HALTER & GRISWOLD LLP

Date: 4/13/04

By: 

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